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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,254

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Eungje Lee

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EXAMINER

EMPIE, NATHAN H

ART UNIT

PAPER NUMBER

1792

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/563,254	Applicant(s) LEE ET AL.	
	Examiner NATHAN H. EMPIE	Art Unit 1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/4/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/4/06, 3/24/06, 8/25/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of 1/4/06 preliminary amendment to the specification which was entered into the file. Claims 1-9 are currently pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokogawa et al. (JP 04-144984, and translated abstract as supplied by applicant in IDS dated 3/24/06; hereafter Yokogawa).

Claim 1: Yokogawa teaches a method of preparing a bioactive ceramic-coated composite, (see, for example, abstract), the method comprising:

coating calcium-phosphate-based ceramic on a ceramic substrate (such as calcium hydroxyapatite film on a ceramic surface, see, for example, abstract);

and thermally treating the coated calcium phosphate-based ceramic layer while supplying water vapor (a thermal reaction is conducted in an atmosphere of steam, see, for example, abstract, therefore water vapor must be "supplied" for treatment).

Claim 2: Yokogawa further teaches wherein the ceramic substrate is formed of at least zirconia (see, for example, embodiment on pg 2, wherein the substrate is a stabilized zirconia).

Claim 4: Yokogawa further teaches wherein the coating of the calcium phosphate based ceramic layer is formed of hydroxyapatite (see, for example, abstract).

Claim 6: Yokogawa further teaches wherein the thermally treating of the coated layer is performed at a temperature of 900 to 1350°C (See, for example, abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokogawa as applied to claim 1 above, and further in view of Piveteau et al. (US patent 6,221,111; hereafter Piveteau)

Claim 3: Yokogawa teaches the method of claim 1, but does not explicitly teach the thickness of the coated layer is about 0.1 micron to 1 mm. Piveteau teaches a method of applying a calcium-phosphate-based coating such as hydroxyapatite onto a substrate (see for example, abstract, col 2 lines 1 – 32). Piveteau further teaches wherein the optimal range for impermeable and porous hydroxyapatite containing layers are preferably 0.5 to 20 microns and 100 microns to 1 mm for impermeable and porous coating layers respectively (see, for example, col 2 lines 20 – 30). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to have incorporated a coating thickness of 0.5 to 20 microns or 100 microns to 1mm for the

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coating thickness of Yokogawa, as Piveteau has taught such ranges will predictably perform the desired bioactive functionality, and since Yokogawa was silent as to an appropriate thickness, when a primary reference is silent as to a certain detail, one of ordinary skill would be motivated to consult a secondary reference which satisfies the deficiencies of the primary reference.

Claim 5: Yokogawa teaches the method of claim 1, and further teaches wherein the coating is prepared by a wet chemical method, forming a slurry (see, for example, abstract). But Yokogawa does not explicitly teach wherein the coating of the calcium phosphate-based ceramic layer is performed using at least one selected from the group consisting of a dipping process, a doctor blade process, PVD, CVD, and a biomimetic coating process. Piveteau teaches a method of applying a calcium-phosphate-based coating such as hydroxyapatite onto a substrate via a wet chemical method (see for example, abstract, col 1 line 50 – col 2 line 32). Piveteau further teaches wherein it is well known in the art that dip coating can be used to predictably to apply a calcium phosphate based coating via a wet chemistry process to a substrate (see, for example, col 2 lines 54 - 61). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to have applied the coating of Yokogawa via a dip coating method as Piveteau has taught dipcoating is a well known and predictable method of applying a calcium phosphate-based coating from a wet-chemistry method.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokogawa as applied to claim 1 above, and further in view of Bernache-Assollant et al.

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("Sintering of Calcium Phosphate Hydroxyapatite $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ I. Calcination and Particle Growth" Journal of the European Ceramic Society 23 (2003) 229-241; hereafter Bernache).

Claim 7: Yokogawa teaches the method of claim 1, but does not explicitly teach the supplying of the water vapor is performed under a partial pressure of 10^{-4} to 1 atmospheric pressure. Bernache teaches that partial pressure of water vapor during a thermal treatment influence the kinetic behavior of hydroxyapatite, therefore the partial pressure of water vapor is a result effective variable (see, for example, abstract, pg231 - 233). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to have incorporated supplying of the water vapor under a partial pressure of 10^{-4} to 1 atmospheric pressure into the method of Yokogawa since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Claim 8: Yokogawa teaches the method of claim 1, but does not explicitly teach wherein the supplying of water vapor comprises incorporating at least one gas selected from the group consisting of O_2 , N_2 , and Ar into water and flowing the gas above the coated layer. Bernache teaches a method heat treating hydroxyapatite materials with water vapor (see, for example, abstract, pg 229-231). Further Bernache teaches it is well known in the art to predictably deliver water vapor with an inert carrier gas such as O_2 (see, for example, pg 231). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to have supplied water vapor by incorporating O_2 ,

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as Bernache has taught that O₂ serves as a carrier gas for water vapor in the heat treatment of hydroxyapatite.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yokogawa as applied to claim 1 above, and further in view of Gross et al. ("Sintered Hydroxyfluorapatites. Part III: Sintering and Resultant Mechanical Properties of Sintered Blends of Hydroxyapatite and Fluorapatite" Biomaterials 25 (2004) 1395-1405, issue 7-8 March-April, available online 6 Nov 2003; hereafter Gross).

Claim 9: Yokogawa teaches the method of claim 1, but does not explicitly teach wherein the supplying of water vapor comprises supplying the water vapor generated by boiling water to the coating layer. Gross teaches a method of thermally treating hydroxyapatite materials in water vapor environments (see, for example, pg 1395-1396). Gross teaches it is well known in the art to predictably supply water vapor in a thermal treatment cycle by passing the gas through boiling water (see, for example, pg 1396). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to have supplied the water vapor by boiling water, as it is a predictable method of obtaining water vapor to treat hydroxyapatite materials.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN H. EMPIE whose telephone number is (571)270-1886. The examiner can normally be reached on M-F, 7:00- 4:30 EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Cleveland can be reached on (571) 272-1418. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H. E./
Examiner, Art Unit 1792

/Katherine A. Bareford/
Primary Examiner, Art Unit 1792